REPORT BY THE

AUDITOR GENERAL

OF CALIFORNIA

THE LABORATORY FIELD SERVICES WITHIN THE DEPARTMENT OF HEALTH SERVICES IS NOT MEETING ALL OF ITS RESPONSIBILITIES TO REGULATE CLINICAL AND PHYSICIANS' LABORATORIES

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The Laboratory Field Services Within the Department of Health Services Is Not Meeting All of Its Responsibilities To Regulate Clinical and Physicians' Laboratories

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Office of the Auditor General
California

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Honorable Elihu M. Harris, Chairman
Members, Joint Legislative Audit Committee
State Capitol, Room 2148
Sacramento, California 95814

Dear Mr. Chairman and Members:

The Office of the Auditor General presents its report concerning the Laboratory Field Services within the Department of Health Services. The report indicates a need for increased monitoring of proficiency test results submitted by clinical and physicians' laboratories, prompt action by the Laboratory Field Services against those laboratories that have failed three or more quarters of proficiency tests, compliance with the statutory formula for the annual calculation of license fees for clinical laboratories and clinical laboratory personnel, and prompt endorsement and deposit of fees received for license renewals for clinical laboratories and clinical laboratory personnel.

Respectfully submitted,

Kurt R. Sjoberg
Acting Auditor General

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Results in Brief

State law and regulations require that the Laboratory Field Services, which is within the Division of Laboratories in the Department of Health Services (department), ensure that all licensed clinical laboratories are maintained and operated without injury to the public and that laboratories have the proper facilities, quality control procedures, and licensed personnel. The Laboratory Field Services determines compliance through on-site inspections and evaluation of mandated proficiency tests conducted by approved proficiency testing services. During our review of the Laboratory Field Services, we found the following conditions:

- In calendar year 1988, the Laboratory Field Services evaluated proficiency test results for only 360 (about 22 percent) of the 1,625 laboratories that are required to participate in proficiency testing;

- The Laboratory Field Services does not have a procedure to determine whether all of the 1,928 laboratories operated by physicians for their own patients (physicians' laboratories) are participating in proficiency testing as required;

- The Laboratory Field Services has not evaluated any of the proficiency test results received from physicians' laboratories;

- The Laboratory Field Services has not always required laboratories that have failed proficiency tests for three quarters to stop providing the applicable diagnostic tests to the public;

- The department has not correctly calculated annual license fees for clinical laboratories and clinical laboratory personnel and, as a result, we estimate that the department undercharged these licensees at least $1.3 million from calendar year 1985 through calendar year 1988; and

- The department has not promptly endorsed and deposited checks, money orders, and warrants submitted as license fees by clinical laboratories and clinical laboratory personnel.

Background

Among other duties, the Laboratory Field Services is responsible for ensuring that laboratories comply with state laws and regulations that relate to clinical laboratories. The Laboratory Field Services also ensures compliance with federal regulations for those laboratories that participate in the Medicare and Medicaid programs operated by the U.S. Department of Health and Human Services.

The Laboratory Field Services staff issue licenses for clinical laboratories and clinical laboratory personnel. In fiscal year 1987-88, the department issued licenses to approximately 2,000 facilities and approximately 25,000 individuals. The Laboratory Field Services staff issue a license to a facility only after an examiner verifies that the laboratory meets requirements concerning the proper facilities, quality control procedures, personnel, and supervision. Similarly, the Laboratory Field Services staff issue licenses to clinical laboratory personnel only after verifying that applicants have met the State's requirements concerning education and training and that the applicants have passed a licensing examination.

The Laboratory Field Services monitors laboratories to verify that they are operating as required. This monitoring includes onsite inspections of clinical laboratories and an evaluation of proficiency test results submitted for certain diagnostic tests conducted by a laboratory.

As part of this audit, we were asked to review the revenues and expenditures of the Laboratory Field Services. The Legislature expressed concern about discrepancies in fiscal information that

had been provided to it regarding the Laboratory Field Services' operations in fiscal year 1986-87. In Appendix D, we present Table D-1, which shows the estimated revenues and expenditures of the Laboratory Field Services from fiscal year 1985-86 through fiscal year 1988-89. As the table shows, during this period, the total expenditures of the Laboratory Field Services closely matched the total revenues that it received.

Only About 22 Percent of Proficiency Test Results for Clinical Laboratories Were Evaluated

The Laboratory Field Services is responsible for ensuring that laboratories are accurately performing the diagnostic tests that the laboratories have been approved to perform. To do this, the Laboratory Field Services relies on a program of proficiency testing in which laboratories are sent test samples that the laboratories are expected to accurately analyze once a quarter. The Laboratory Field Services evaluates the laboratories' performance on proficiency tests.

However, in calendar year 1988, the Laboratory Field Services staff reviewed the proficiency test results for only 360 (about 22 percent) of the 1,625 clinical laboratories that are required to participate in proficiency testing. According to the chief of the Laboratory Field Services, the Laboratory Field Services does not have enough staff to evaluate all the proficiency test results it receives. However, when the Laboratory Field Services does not evaluate the laboratories' performance on the proficiency tests, it cannot identify and take appropriate actions against laboratories that may not be proficient in performing their diagnostic tests; consequently, these laboratories may be presenting a risk to those who rely on their services.

The department is continuing efforts that it began in 1975 toward developing an automated system that will evaluate proficiency test results. However, the automated system has not yet been fully developed. The chief of the Data Systems Branch currently estimates that the first phase of an automated system for the evaluation of proficiency tests will begin to be used for some tests in 1990.

No Procedure To Determine Whether All Physicians' Laboratories Participate in Proficiency Testing and No Evaluation of Results for Physicians' Laboratories

According to the California Business and Professions Code, physicians' laboratories are required to participate in proficiency testing and demonstrate satisfactory performance for those diagnostic tests that they perform. However, the Laboratory Field Services does not have a procedure to determine whether all physicians' laboratories are successfully participating in proficiency testing. Of a sample of 334 physicians' laboratories, 129 (38.6 percent) were not listed in the enrollment records of any of the three proficiency testing services. According to the deputy director of Public Health within the Department of Health Services, the department does not have a procedure to determine what diagnostic tests are performed by physicians' laboratories. As a result, the department does not know if these 129 physicians' laboratories perform diagnostic tests for which proficiency testing is required. In addition, the Laboratory Field Services has not evaluated proficiency test results for any of 1,928 physicians' laboratories listed in Laboratory Field Services' records as of December 1988. According to the chief of the Laboratory Field Services, the Laboratory Field Services does not have enough staff to evaluate tests from physicians' laboratories. When the Laboratory Field Services cannot determine whether physicians' laboratories are proficient in performing the diagnostic tests that they make available to the public, it cannot identify and take appropriate actions against those laboratories that may not be proficient in performing diagnostic tests; consequently, these laboratories may be presenting a risk to those who rely on their services.

Action Not Always Taken Against Laboratories That Have Failed Proficiency Tests

The Laboratory Field Services can require that laboratories that have failed proficiency tests for three quarters stop providing these diagnostic tests to the public. However, for 40 (70.2 percent) of 57 laboratories that we sampled that the Laboratory Field Services had identified as having failed one or more proficiency tests for three consecutive quarters, the Laboratory Field Services did not direct these laboratories to stop providing these diagnostic tests. When the Laboratory Field Services does not take action against laboratories that have failed proficiency tests, it allows these laboratories to continue to offer diagnostic tests even though they may not be proficient in performing them, thereby, presenting a risk to those who rely on their services.

Incorrect Calculation of Annual License Fees

The California Health and Safety Code specifies the formula that the department is to use in calculating its annual license fees for clinical laboratories and clinical laboratory personnel. However, the department has not correctly applied the formula and, as a result, we estimate that the department has undercharged clinical laboratories and clinical laboratory personnel at least $1.3 million from calendar year 1985 through calendar year 1988. Nevertheless, this additional $1.3 million would not have been directly allocated to the Laboratory Field Services to increase its regulatory activity. Instead, revenues from license fees are remitted to the State's General Fund, from which they are eventually allocated through the State's budgeting process to support a variety of state activities.

No Prompt Endorsement and Deposit of License Renewal Fees

According to state requirements, the department should promptly endorse and deposit the license fees that it collects. The department is required to endorse checks, warrants, and money orders on the same day that it receives them. Similarly, the department is required to deposit the checks, warrants, and money orders totaling $50 or more within five working days of receiving them. However, for a sample of 358 laboratory license renewals, we estimate that the department took an average of approximately 22 days to endorse and deposit the checks, warrants, and money orders. According to the senior administrative analyst of accounting systems, the cashiering group is not able to endorse and deposit fees promptly because state law requires that clinical laboratories and clinical laboratory personnel renew their licenses within 60 days of the annual license expiration on December 31. The senior administrative analyst stated that processing approximately 27,000 license renewal applications in a 60-day period is more than the department's staff can handle promptly. The department estimates that, in calendar year 1989, the department incurred costs of approximately $6,200 for employee overtime to process the approximately 27,000 licenses within the 60-day period.

Recommendations

To improve its evaluation of laboratories' proficiency test results and its calculation, endorsement, and deposit of license fees, the Department of Health Services and the Laboratory Field Services should take the following actions:

- Continue to develop an automated system to evaluate proficiency test results;

- Promptly evaluate all proficiency test results for clinical laboratories and physicians' laboratories. To do this, the Laboratory Field Services should hire additional staff until the automated system is operational;

- Develop a procedure to verify that physicians' laboratories are enrolled in proficiency testing for all diagnostic tests that the Laboratory Field Services monitors;

- Require all laboratories that fail proficiency tests to stop providing the applicable diagnostic tests to the public as soon as the staff at the Laboratory Field Services determine that the laboratories are not passing the proficiency tests;

- Properly apply the formula described in the Health and Safety Code to calculate the license fees for clinical laboratories and clinical laboratory personnel; and

- Seek legislation that would allow for staggered expiration of licenses so that the work load of the department's cashiering group would be distributed more evenly throughout the year and, thus, allow the cashiering group to promptly endorse and deposit fees.

Agency Comments

The Department of Health Services agrees with the findings that we present in our report and plans to implement each of our recommendations. In its response, the department stated that it has already implemented the recommendation that we made concerning the proper calculation of license fees for clinical laboratories and clinical laboratory personnel.

Introduction

The Department of Health Services (department) administers California's clinical laboratory licensing program. The Laboratory Field Services within the department's Division of Laboratories is responsible for ensuring that clinical laboratories comply with the laws and regulations that relate to clinical laboratories. Clinical laboratories are laboratories that conduct diagnostic tests on tissue and other substances obtained from the human body at the request of physicians. These diagnostic tests assist physicians in monitoring the health of their patients and in diagnosing medical conditions affecting these patients.

Clinical laboratories are located in hospitals or may exist as independently operated facilities. Some clinical laboratories are operated within a physician's office by a physician for his or her own patients. In this report we will refer to laboratories operated in physicians' offices as "physicians' laboratories." We will refer to all other laboratories as "clinical laboratories." State statutes exempt physicians' laboratories from the requirement to obtain a license from the department. However, physicians' laboratories are required to participate in proficiency tests for certain diagnostic tests that they provide to their patients. (See pages 16-17 of this report for a detailed description of proficiency testing).

Licensing

The state statutes and regulations that established the clinical laboratory licensing program require that, with a few exceptions including physicians' laboratories, clinical laboratories be li-

censed. Before issuing licenses, examiners from the Laboratory Field Services conduct on-site inspections to verify that the laboratories meet minimum requirements. Licensed laboratories must submit an application and fees to have their license renewed once each year following the expiration of the annual license on December 31. No inspection is required for the renewal license to be issued.

In addition to licensing clinical laboratories, the department issues licenses to clinical laboratory personnel such as trainees, technologists, and laboratory directors. Applicants for clinical laboratory personnel licenses receive licenses only after the staff at the Laboratory Field Services have reviewed personnel license applications, have determined that the applicants have met education and training requirements, and have tested applicants. Licensed clinical laboratory personnel must submit an application and fees to have their license renewed once each year following the expiration of the annual license on December 31. The department does not require any reexamination or any continuing education for a renewal license to be issued.

Inspections and Proficiency Testing

To ensure that licensed clinical laboratories only utilize licensed professionals and to assess laboratory compliance with regulations, the department conducts unannounced, on-site laboratory inspections. During these inspections, an examiner from the Laboratory Field Services will evaluate a laboratory to determine whether it is in substantial compliance with laws and regulations. Appendix A provides more detailed information on the clinical laboratory and clinical laboratory personnel licensing programs conducted by the Laboratory Field Services and the inspection of clinical laboratories by the examiners of the Laboratory Field Services.

The department also evaluates a laboratory's ability to provide reliable diagnostic tests by evaluating the laboratory's quarterly performance on proficiency tests. Physicians' laboratories,

as well as clinical laboratories, must demonstrate satisfactory performance on proficiency tests. Proficiency testing is a form of quality control that involves an approved proficiency testing service mailing test samples to a laboratory for analysis. The test samples may contain substances in types or in amounts unknown to the laboratory. The laboratory tests the samples and sends the test results to the proficiency testing service for evaluation. The proficiency testing service determines whether the results meet the grading criteria established by the proficiency testing service and are, therefore, acceptable. The proficiency testing service sends the results to the Laboratory Field Services, where staff evaluate the laboratory's performance on the proficiency test. If a laboratory has test results that are not within the acceptable range for three consecutive quarters, the department can suspend a laboratory from offering a diagnostic test to the public.

In addition to ensuring that the licensed laboratories and personnel meet state requirements, the department also implements the contractual agreement that the federal government has made with the State of California. This contract requires that the department administer certain requirements related to laboratories that participate in the Medicare and Medicaid programs. (Throughout this report, we will refer to these laboratories as "Medicare laboratories.") This contract currently requires that the department annually inspect 60 percent of the laboratories that are covered by the contract. In addition, the contract requires that the department evaluate the quarterly proficiency test results for all laboratories that are covered by the contract.

Enforcement Actions

When the Laboratory Field Services determines that a laboratory has not complied with licensing requirements, it initiates action to ensure that the laboratory corrects any deficiencies or stops providing the applicable diagnostic test to the public. Specifically, when an examiner from the Laboratory Field Services determines during a laboratory inspection that a laboratory does not have the required facilities, quality control procedures, per-

sonnel, and supervision to perform a diagnostic test, the Laboratory Field Services will notify the laboratory of the problem and request that the laboratory formulate a plan of corrective action. The laboratory must submit a plan of corrective action to the department within ten days. If the corrective action plan is not submitted, or if the laboratory does not take the actions listed in the corrective action plan, the department can require that the laboratory stop providing the applicable diagnostic test. Similarly, when staff at the Laboratory Field Services evaluate a laboratory's performance on a proficiency test and determine that a laboratory is not within the acceptable range for three quarters in a row, the staff can require a laboratory to stop providing the diagnostic test to the public until it can pass the proficiency test for two consecutive quarters.

Although most disciplinary actions taken by the department are limited to requests for a laboratory to improve its operation or stop providing a diagnostic test to the public, the department can take other action against a laboratory and laboratory personnel, including the suspension or forfeiture of a license. This action can result from the commission of a felony or other violations of statute. Appendix B contains a listing of the cases referred to the department's Office of Legal Services by the Laboratory Field Services from January 1, 1985, to August 19, 1989.

New Laws Governing the Regulation of Clinical Laboratories

According to a 1988 Washington Post article, since about 1987, the public has become increasingly concerned about the accuracy of diagnostic tests performed in clinical and physicians' laboratories. The article stated that these concerns have focused on the analysis of employee drug tests, the Pap smear test for detecting cervical cancer, blood serum tests for cholesterol levels, and tests to detect the presence of antibodies to the Acquired Immune Deficiency Syndrome (AIDS) virus. Furthermore, a 1987 Wall Street Journal article alleged that Pap smear tests failed to reveal cervical cancer or cell abnormalities 20 to 40 percent of the time.

To determine the rate of error of Pap smear tests in California, in 1989 the Laboratory Field Services conducted a study of ten randomly selected laboratories that evaluate Pap smear slides. As part of the study, survey teams examined 3,312 Pap smear slides and determined that the overall error rate for these ten laboratories was between 0.32 and 4.73 percent.

In 1988, the U.S. Congress enacted the Clinical Laboratory Improvement Amendments of 1988 that require inspection and monitoring of all laboratories. In addition, in 1989, the State of California enacted a new statute that will increase the requirements for laboratories that evaluate samples obtained in Pap smear tests. For example, the statute requires, among other things, that the department issue licenses to individuals who will examine Pap smear slides on or after January 1, 1991, and establish standards for these individuals to evaluate the slides. In addition, the Laboratory Field Services must establish standards for a proficiency testing program for clinical laboratories examining Pap smear slides. Finally, the statute limits the number of slides that a licensee can examine within a 24-hour period.

Scope and Methodology

The purpose of this audit was to provide information on the Laboratory Field Services. During the audit, we reviewed the Laboratory Field Services' regulation of clinical and physicians' laboratories and clinical laboratory personnel in California. In addition, we reviewed the department's process for calculating the license fees that are paid by clinical laboratories and laboratory personnel and its process for endorsing and depositing the fees that it receives from licensees. Also, we collected information on each of the Laboratory Field Services' sources of revenue and information on each of the regulatory and administrative activities on which the Laboratory Field Services spends its revenue.

To evaluate the Laboratory Field Services' regulation of the State's clinical and physicians' laboratories and clinical laboratory personnel, we reviewed applicable statutes and regulations, interviewed staff from the Laboratory Field Services, the Department of Health Services, and the U.S. Department of Health and Human Services, and validated information from several of the Laboratory Field Services' operational and financial data bases.

More specifically, to evaluate the Laboratory Field Services' monitoring of the laboratories' participation in proficiency testing, we validated information provided to us by the Laboratory Field Services on the number of laboratories for which the Laboratory Field Services had evaluated proficiency tests. We determined that the Laboratory Field Services evaluated proficiency test results received for 360 laboratories in calendar year 1988. One proficiency testing service reported the results for 303 of these laboratories. For these 303 laboratories, we determined how many had not passed their proficiency tests and what action was taken by the Laboratory Field Services as a result.

To evaluate the department's annual calculation of the licensing fees, we first reviewed the statute that outlines the formula that the department is required to follow in calculating the annual adjustment. Relying on this formula, we then calculated the adjustment for calendar year 1985 through calendar year 1988. In Appendix C, we provide information on how the department calculates license fees each year.

To evaluate the processing of the license fees, we reviewed the department's endorsement and deposit of a sample of fees received. We determined for these fees whether the department processed these fees in accordance with state guidelines.

To evaluate the Laboratory Field Services' inspection of clinical laboratories, we first familiarized ourselves with the inspection process by accompanying an examiner on an inspection. We then verified information regarding the date of the last

inspection of each laboratory by the Laboratory Field Services. Furthermore, for a sample of 123 laboratories, we determined whether these laboratories eventually corrected deficiencies that the Laboratory Field Services had identified during the last inspection.

Finally, as part of this audit, we were asked to review the revenues and expenditures of the Laboratory Field Services. The Legislature expressed concern about discrepancies in fiscal information that had been provided to it regarding the Laboratory Field Services' operations in fiscal year 1986-87. To resolve this concern, we obtained department data on the revenues and expenditures of the Laboratory Field Services for fiscal year 1985-86 through fiscal year 1988-89. In addition, we list the various activities the Laboratory Field Services staff spent their time on during this period. We present this information in Appendix D.

Chapter 1 The Laboratory Field Services' Oversight of Laboratory Participation in Proficiency Testing Has Been Limited

Chapter Summary

State law requires that all clinical and physicians' laboratories successfully perform proficiency tests for the diagnostic tests that they provide to the public. However, during calendar year 1988, the staff of the Laboratory Field Services, within the Department of Health Services (department), evaluated the proficiency test results received for only about 22 percent of the clinical laboratories. In addition, the Laboratory Field Services does not have a procedure to determine whether all laboratories operated by physicians for their own patients (physicians' laboratories) are participating in proficiency testing as required. Furthermore, the Laboratory Field Services staff have not evaluated any of the proficiency test results received from physicians' laboratories. Finally, the Laboratory Field Services does not always require laboratories that have failed proficiency tests for three quarters to stop providing the applicable diagnostic tests to the public.

When the Laboratory Field Services does not evaluate each laboratory's performance on proficiency tests and does not have a procedure to determine whether all physicians' laboratories are participating in proficiency testing, it is not able to identify those laboratories that are unable to accurately perform certain diagnostic tests and that, therefore, may be presenting a risk to those who rely on their services. The Laboratory Field Services is also putting the public at risk when it does not require laboratories that have failed proficiency tests to stop providing diagnostic tests to the public. The Laboratory Field Services currently has only one staff person assigned to evaluate proficiency test results. Since 1975, the department has been attempting to resolve its

inability to evaluate proficiency tests by developing an automated system to evaluate them. However, the automated system is not yet operational.

Background

Proficiency testing is a form of quality control designed to assess a laboratory's ability to accurately perform the diagnostic tests that it performs. Each quarter, an approved testing service sends test samples to the laboratory. The laboratory analyzes the test samples and sends the results of its analysis to the proficiency testing service. The proficiency testing service then determines whether the laboratory's analytical results fall within an acceptable range. The proficiency testing service then sends the results of its determination to the laboratory and to the Laboratory Field Services.

Staff of the Laboratory Field Services evaluate laboratories' performance on quarterly proficiency tests by reviewing the test results received from the proficiency testing services. According to Section 1050(b) of the California Code of Regulations, if the department determines that a laboratory's performance on the proficiency test for three consecutive quarters is not within an acceptable range, the department can require the laboratory to stop providing the diagnostic test to the public.

The California Business and Professions Code requires that clinical and physicians' laboratories participate in state-approved proficiency testing programs. Although the clinical and physicians' laboratories must participate in state-approved proficiency testing programs, each laboratory can choose what proficiency testing service to use. The department has approved three proficiency testing services to be used by laboratories. Laboratories enroll with one of the three proficiency testing services and make arrangements to receive test samples to analyze each quarter for many of the diagnostic tests that the laboratories provide. The laboratories pay for the tests that they will receive

and are required by regulation to have the proficiency testing service report test results to the department.

Only About 22 Percent of Proficiency Test Results for Clinical Laboratories Were Evaluated

According to Section 1220 of the California Business and Professions Code, the department, through regulation, should require all clinical and physicians' laboratories to demonstrate satisfactory performance in an approved proficiency testing program. Therefore, it follows that the department should review all proficiency test results that it receives.

The Laboratory Field Services estimates that in calendar year 1988, it evaluated proficiency test results for only 360 (about 22 percent) of the 1,625 clinical laboratories that have proficiency tests that should be evaluated by the Laboratory Field Services. The majority of these test results were for laboratories that participate in the Medicare and Medicaid programs (Medicare laboratories) and that were enrolled in only one of the three proficiency testing services.

For each quarter, this proficiency testing service reports all of its test results for a laboratory on one document. However, the other two testing services report results by series of diagnostic tests rather than by laboratory, which means that the Laboratory Field Services staff may have to review up to ten different reports to evaluate all of the proficiency test results for one laboratory for one quarter. According to the chief of the Laboratory Field Services, one staff person is assigned to evaluate proficiency test results, and one person cannot evaluate all of the proficiency test results received for clinical laboratories and physicians' laboratories. Therefore, the Laboratory Field Services staff generally limit their evaluation activity to the results reported by the one proficiency testing service that reports the results by laboratory. According to the deputy director of Public Health within the Department of Health Services, the department has not authorized the Laboratory Field Services to create any additional positions for staff to monitor proficiency tests. In addition, the deputy director stated that the reasons why the department has

not authorized additional positions include the fact that an automated system to monitor proficiency tests is being implemented and that there have been other higher priorities for the department's limited general fund allocation.

No Procedure To Determine Whether All Physicians' Laboratories Participate in Proficiency Testing and No Evaluation of Results for Physicians' Laboratories

According to the California Business and Professions Code, physicians' laboratories are required to participate in proficiency testing and demonstrate satisfactory performance for their diagnostic tests. We attempted to determine whether physicians' laboratories were enrolled in proficiency tests. We reviewed a sample of 334 (17.3 percent) of 1,928 physicians' laboratories and determined that 129 (38.6 percent) of the laboratories were not listed in enrollment records of any of the three proficiency testing services. According to the deputy director of Public Health within the Department of Health Services, the department does not have a procedure to determine what diagnostic tests are performed by physicians' laboratories.

When a physician's laboratory first contacts the Laboratory Field Services, the staff at the Laboratory Field Services inform the physician's laboratory of the requirement to participate in proficiency testing. It is then the laboratory's responsibility to enroll in proficiency testing with one of the three proficiency testing services and to notify the Laboratory Field Services of this enrollment. Physicians' laboratories are exempt from the statute that requires licensing, and so the examiners from the Laboratory Field Services do not perform on-site inspections of physicians' laboratories as they do of clinical laboratories. During on-site inspections of clinical laboratories, inspectors determine which diagnostic tests the laboratories perform. However, the Laboratory Field Services cannot obtain this information for physicians' laboratories because it does not inspect them. As a result, the Laboratory Field Services does not know if the physicians' laboratories perform diagnostic tests for which proficiency testing is required. Additionally, the Laboratory Field Services has not evaluated any proficiency test results that it has received for

1,928 physicians' laboratories listed in Laboratory Field Services' records as of December 1988. According to the chief of the Laboratory Field Services, the Laboratory Field Services does not have enough staff to evaluate test results for physicians' laboratories.

Action Not Always Taken Against Laboratories That Have Failed Proficiency Tests

The Laboratory Field Services has not always required laboratories that have failed the proficiency tests for three consecutive quarters to stop providing the applicable diagnostic tests to the public. We reviewed the Laboratory Field Services' records for all Medicare laboratories that had proficiency test results reported by the one proficiency testing service that reports results by laboratory. As of December 31, 1988, the Laboratory Field Services staff determined that 57 (18.8 percent) of the 303 Medicare laboratories evaluated by one proficiency testing service had failed one or more proficiency test samples for three consecutive quarters. However, as of July 1989, the department had only notified 17 (29.8 percent) of these 57 laboratories that they must stop offering the diagnostic test or tests to the public.

According to the chief of the Laboratory Field Services, the Laboratory Field Services did not notify the remaining 40 laboratories to stop providing the diagnostic test to the public because, during the six-month or more delay between when the Laboratory Field Services received the proficiency test results and when the Laboratory Field Services staff evaluated these results, the Laboratory Field Services had received proficiency test results for at least two additional quarters. A laboratory that has failed proficiency testing for three consecutive quarters and has been directed by the Laboratory Field Services to stop offering diagnostic tests can become reinstated by successfully completing its proficiency tests for two consecutive quarters. Therefore, the Laboratory Field Services did not want to direct the 40 laboratories to stop offering diagnostic tests while the possibility existed that these laboratories had improved their proficiency test scores

in the two additional quarters of proficiency testing.

For the 40 laboratories, we reviewed the proficiency test results for the two quarters subsequent to the third quarter of unsuccessful participation in a proficiency test. Twenty-five (62.5 percent) of the 40 laboratories did improve and passed the subsequent two quarters of proficiency testing. An additional 3 laboratories stopped providing the test to the public or the laboratories closed. However, as of July 1989, the Laboratory Field Services still had not yet required 12 (21.1 percent) of the 57 laboratories that had failed one or more proficiency test samples for three consecutive quarters to stop offering a diagnostic test to the public even though these laboratories had failed the proficiency test for four or more quarters.

Effects of Limited Oversight

When the Laboratory Field Services does not evaluate proficiency test results for all clinical and physicians' laboratories and does not have a procedure to determine whether all physicians' laboratories are participating in proficiency testing, the Laboratory Field Services cannot identify and take appropriate action against those laboratories that may not be proficient in performing diagnostic tests and that, therefore, may be presenting a risk to those who rely on their services. The Laboratory Field Services is also putting the public at risk when it does not take prompt action against those laboratories that have not successfully participated in proficiency testing. However, the department has taken steps to increase its oversight of proficiency testing.

Actions Taken To Improve Oversight of Proficiency Testing

In March 1988, the department released a feasibility study report that assesses the feasibility of converting the proficiency test evaluation to an automated system. In this report, the department concluded that, in the long run, the preferred alternative for improving its evaluation of proficiency test results would be to convert to an automated system from the current manual system.

The department estimated that the Laboratory Field Services would need the equivalent of approximately eight staff to manually evaluate all proficiency test results received. This 1988 report estimated the cost of the additional staff would be approximately $235,500 annually while the "onetime" cost of developing an automated system would be $306,200 with annual processing costs of $32,400.

As a result, the department is continuing efforts that it began in 1975 to develop an automated system that will evaluate proficiency test results. According to the chief of the department's Data Systems Branch, the delays in developing the system have resulted, in part, from delays in obtaining proficiency test results from the three state-approved proficiency testing services in a format that would be usable in an automated environment. More recently, the largest proficiency testing service has cooperated with the department to overcome this problem and currently supplies all of its quarterly results to the department in formats that are usable in an automated system. In 1988, the federal government agreed to provide one half of the funding, with a maximum expenditure of $153,100 for the development of an automated system for the evaluation of proficiency test results. The chief of the Data Systems Branch currently estimates that an automated system will begin to be used for some proficiency tests in 1990.

However, the Clinical Laboratory Improvement Amendments of 1988, passed by the U.S. Congress, will result in some changes in the requirements for laboratory participation in proficiency testing and may have an impact on the department's evaluation of proficiency tests. According to these amendments, the secretary of the U.S. Department of Health and Human Services must establish uniform criteria for laboratories in all states for acceptable performance under a proficiency testing program. In addition, the nationwide standards are required to include a system for grading proficiency testing performance to determine whether

a laboratory has performed acceptably for a particular diagnostic test over a period of successive quarters. Furthermore, the act requires the secretary to establish a system to make the results of the proficiency testing programs available to the public upon request. These requirements will take effect on January 1, 1990. According to the director of the Office of Survey and Certification of the Health Care Financing Administration of the U.S. Department of Health and Human Services, to meet the requirements of this act, the federal government may be developing an automated system to standardize the evaluation and reporting of the proficiency test results for all 50 states. Therefore, work by the department to automate the review of proficiency test results may duplicate a system that will eventually be provided by the federal government. Consequently, to ensure that the automated system that the department is developing will be consistent with the new federal requirements, the State needs to coordinate its efforts to automate the evaluation of proficiency tests with the federal government.

Conclusion

The Laboratory Field Services' oversight of laboratory participation in proficiency testing has been limited. By its own estimate, during calendar year 1988, the Laboratory Field Services evaluated only about 22 percent of the proficiency test results that it received. Additionally, the Laboratory Field Services does not have a procedure to determine whether all physicians' laboratories participate in proficiency testing as required, and it has not evaluated any of the proficiency test results received from physicians' laboratories. Furthermore, even when it does evaluate proficiency test results, the Laboratory Field Services does not always direct laboratories that have failed their proficiency tests for three consecutive quarters to stop providing these diagnostic tests to the public. As a result, the Laboratory Field Services cannot ensure that clinical laboratories and physicians' laboratories only provide diagnostic tests for which they have passsed proficiency tests. Therefore, the Laboratory Field Services is not able to ensure that some laboratories accurately perform certain diagnostic tests. Consequently, these laboratories may be presenting a risk to those who rely on their services.

Recommendations

To provide greater assurance that laboratories are proficient in the diagnostic tests that they are providing to the public, the Laboratory Field Services should take the following actions:

- Continue to develop an automated system to evaluate proficiency test results as long as the new system will be compatible with new federal requirements that will be taking effect in 1990;

- Promptly evaluate all proficiency test results for clinical laboratories and physicians' laboratories. To do this, the Laboratory Field Services should obtain additional staff until the automated system is operational;

- Develop a procedure to verify that physicians' laboratories are enrolled in proficiency testing for all diagnostic tests that the Laboratory Field Services monitors; and

- Require all laboratories that fail proficiency tests to stop providing the applicable diagnostic tests to the public as soon as the staff at the Laboratory Field Services determine that the laboratories are not passing the proficiency tests.

Chapter 2 The Department of Health Services Has Not Always Complied With State Laws and Regulations in Calculating and Depositing the License Fees That It Collects From Clinical Laboratories and Clinical Laboratory Personnel

Chapter summary

Section 116 of the Health and Safety Code outlines the formula that the Department of Health Services (department) is to follow in calculating the license fees that it collects from clinical laboratories and clinical laboratory personnel. However, the department has not correctly applied the formula and, as a result, we estimate that the department has undercharged clinical laboratories and clinical laboratory personnel at least $1.3 million from calendar year 1985 through calendar year 1988. Nevertheless, this additional $1.3 million would not have been directly allocated to the Laboratory Field Services to increase its regulatory activity. Instead, revenues from license fees are remitted to the State's General Fund, from which they are eventually allocated through the State's budgeting process to support a variety of state activities.

Additionally, the department has not complied with requirements of the State Administrative Manual to promptly endorse and deposit the license renewal fees that it collects from licensees. For a sample of 358 license renewals, we estimate that the department took an average of approximately 22 days to endorse and deposit the checks, warrants, and money orders. According to the senior administrative analyst of accounting systems, the cashiering group is not able to comply with the requirements because Section 1301 of the California Business and Professions Code requires that clinical laboratories and clinical laboratory personnel renew their licenses within 60 days of the annual license expiration on December 31. The senior administrative analyst stated that processing approximately 27,000 license re-

newal applications in a 60-day period is more than the department's staff can handle promptly. The department estimates that, in calendar year 1989, it incurred costs of approximately $6,200 for employee overtime to process the approximately 27,000 licenses within the 60-day period.

Incorrect Calculation of Annual License Fees

Section 116 of the Health and Safety Code specifies the formula that the department is to use in calculating the annual license fees for clinical laboratories and clinical laboratory personnel. As the state budget act requires, the fees increase or decrease to reflect changes in program costs and to reflect changes in federal reimbursement as a percent of total revenues. (Appendix C contains a detailed description of the formula.) Between calendar year 1984 and calendar year 1989, the department has not performed one of the required adjustments in its annual calculation of the license fees. Consequently, between 1984 and 1989, the department has undercharged the clinical laboratories and clinical laboratory personnel for their licenses. When we brought this matter to the attention of the department's Office of Legal Services, a staff attorney acknowledged that in applying the formula the department should perform the adjustment. Although the department has not correctly calculated license fees since 1984, we were only able to estimate the lost revenue for the period from calendar year 1985 through calendar year 1988. We estimate that between 1985 and 1988, the department should have charged clinical laboratories and clinical laboratory personnel at least an additional $1.3 million in license fees. However, this additional $1.3 million would not have been directly allocated to the Laboratory Field Services to increase its regulatory activity. Instead, revenues from license fees are remitted to the State's General Fund, from which they are eventually allocated through the State's budgeting process to support a variety of state activities.

Table 1 compares the amount of license fees actually charged by the department with the amount of license fees that should have been charged for various types of licenses. For example, the table shows that the department charged clinical laboratories $256 each for initial license fees in 1988 instead of the correct charge of $276 each.

Table 1

A Comparison of the Fees That Were Charged for Various Types of Licenses With the Fees That Should Have Been Charged Calendar Year 1985 Through Calendar Year 1988

License Type	1985			1986			1987			1988		
	Fee Charged	Fee According to Statute	Fee Difference	Fee Charged	Fee According to Statute	Fee Difference	Fee Charged	Fee According to Statute	Fee Difference	Fee Charged	Fee According to Statute	Fee Difference
Initial License Fees												
Laboratory director	$ 44	$ 56	$ 12	$ 44	$ 70	$ 26	$ 64	$ 100	$ 36	$ 66	$ 70	$ 4
Clinical laboratory technologist	27	34	7	27	42	15	39	60	21	40	42	2
Clinical laboratory technologist trainee	9	12	3	9	14	5	13	21	8	13	14	1
Clinical laboratory	172	221	49	171	275	104	250	395	145	256	276	20
Renewal License Fees												
Laboratory director	44	56	12	44	70	26	64	100	36	66	70	4
Clinical laboratory technologist	17	22	5	17	28	11	25	40	15	26	28	2
Clinical laboratory technologist trainee	5	7	2	5	9	4	7	13	6	7	9	2
Clinical laboratory	136	175	39	135	218	83	197	312	115	202	218	16

No Prompt Endorsement and Deposit of License Renewal Fees

The department's Laboratory Field Services issues licenses to clinical laboratories and clinical laboratory personnel. According to Section 1301 of the California Business and Professions Code, personnel and facility licenses expire on December 31 each year. The licenses become delinquent in 60 days if the licensee has not submitted the renewal application and fees. The department mails renewal applications to licensees before the expiration of their annual licenses on December 31. The renewal applications state that the renewal applications and the license fees should be mailed to the Department of Health Services in Sacramento.

The cashiering group within the department is responsible for endorsing and depositing license renewal fees. According to the State Administrative Manual, checks, money orders, and warrants must be endorsed by the end of the working day that they are received. The State Administrative Manual also directs that the department deposit accumulated collections of cash totaling $50 or more within five working days of when the cash was received.

We reviewed 358 facility license renewals. We estimate the department took an average of approximately 22 days to endorse and deposit the checks, money orders, and warrants received from the 358 clinical laboratories. Consequently, for our sample, we estimate that the department took approximately 17 days longer to deposit fees than allowed by the State Administrative Manual. When the department is not prompt in endorsing and depositing the fees that it receives from licensees, it loses the interest that it would have earned had it promptly deposited the funds.

According to the senior administrative analyst of accounting systems, the cashiering group is not able to endorse and deposit the license renewal fees more promptly because of the approximately 27,000 clinical laboratory and clinical laboratory personnel license renewals that the department receives within a two-month span of time after the expiration of the licenses on

December 31. Also during this same period, the cashiering group endorses and deposits renewals for other licenses, certificates, accreditations, and permits, such as licenses for radiologists, radiological equipment, and nursing assistants.

Furthermore, the senior administrative analyst stated that because all the clinical laboratory and clinical laboratory personnel licenses expire at the same time, the volume of work is so great that the department authorizes the staff to work overtime. Moreover, the department hires temporary help to assist the permanent staff within the cashiering group to process the renewal applications. The department estimated that between January 1 and March 30, 1989, the department accrued costs of about $6,200 for approximately 480 hours of overtime within the department's cashiering group to process all of the license renewals within the 60-day period following the expiration of licenses.

According to the department's senior administrative analyst of accounting systems, the cashiering group has had similar problems in complying with state regulations for the prompt endorsement and deposit of fees for its radiologic health license program. The department has been able to resolve these problems and has begun to meet state regulations by staggering the license renewal dates. The renewal of radiologic health licenses is required by Section 30408 of the California Code of Regulations. This regulation requires that the annual fees be collected biennially. In 1988, the department changed the expiration date of radiologic health certificates from December 31 of a renewal year to different times throughout the year. The senior administrative analyst stated that staggering the renewal dates of the radiologic health licenses has eased the burden on the cashiering group and greatly facilitated the processing of radiologic health fees.

Conclusion

The Department of Health Services has not calculated clinical laboratory and clinical laboratory personnel license fees according to the statutory formula. As a result, we estimate that, from calendar year 1985 through calendar year 1988, the department did not receive at least $1.3 million that it would have received had license fees been correctly calculated. Also, the department has not complied with the requirements of the State Administrative Manual for the handling of cash receipts. According to the requirements, checks, warrants, and money orders should be endorsed by the department on the date that they are received from the licensees, and cash totaling $50 or more should be deposited in a bank within five working days of receipt. However, we estimate that the department did not endorse or deposit checks, warrants, and money orders until an average of approximately 22 days after receipt. According to the senior administrative analyst of accounting systems, the cashiering group is not able to comply with the requirements because statutes require the department to process license renewal applications for approximately 27,000 clinical laboratory and clinical laboratory personnel licenses in a two-month period, which is more than the staff of the cashiering group can handle promptly. In addition, in processing the license renewals for calendar year 1989, the department accrued costs of approximately $6,200 for approximately 480 hours of overtime within the department's cashiering group to process all of the license renewals within a 60-day period following the expiration of licenses.

Recommendations

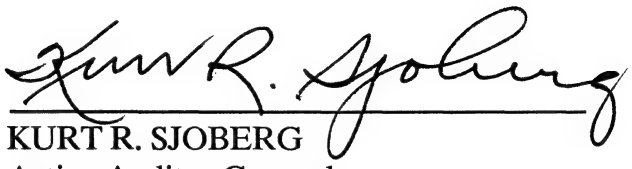
To improve its calculation, endorsement, and deposit of license fees, the Department of Health Services should take the following actions:

- Properly apply the formula described in Section 116 of the Health and Safety Code to calculate the license fees for clinical laboratories and clinical laboratory personnel. Because the formula relies on data from the previous year's calculation of license fees, the department should calculate the 1990 license fees only after correctly applying the statutory formula to all annual fees incorrectly calculated from 1984 through 1989; and

- Seek legislation that would allow for staggered expiration of licenses so that the work load of the department's cashiering group would be distributed more evenly throughout the year and, thus, allow the cashiering group to promptly endorse and deposit fees.

We conducted this review under the authority vested in the auditor general by Section 10500 et seq. of the California Government Code and according to generally accepted governmental auditing standards. We limited our review to those areas specified in the audit scope section of this report.

Respectfully submitted,



KURT R. SJOBERG
Acting Auditor General

Date: December 4, 1989

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Appendix A Responsibilities of the Laboratory Field Services

The Legislature requested that the Office of the Auditor General provide information on the responsibilities of the Laboratory Field Services, within the Department of Health Services (department), including information on how the Laboratory Field Services monitors laboratories' compliance with applicable laws and regulations. This appendix provides information on the clinical laboratory and clinical laboratory personnel licensing programs conducted by the Laboratory Field Services, the laboratory inspections conducted by examiners from the Laboratory Field Services to ensure compliance with statutes and regulations, and how the Laboratory Field Services ensures that laboratories correct any deficiencies identified during the inspections. This appendix also contains a brief description of the responsibilities of the Laboratory Field Services that do not pertain to clinical laboratory or clinical laboratory personnel licensing.

The Licensing Program

State statutes require the licensing of clinical laboratories, with a few exceptions including laboratories operated by physicians for their own patients (physicians' laboratories). To become licensed, these laboratories must meet minimum requirements that include that the laboratories demonstrate that they have proper facilities, quality control procedures, personnel, and supervision and that they have established procedures for examining specimens, performing related activities, ensuring the accuracy of test results, and maintaining an historical record of the test results for at least two years. Before issuing a laboratory license,

examiners of the Laboratory Field Services conduct an inspection of the laboratory to determine whether the licensing requirements have been met.

In addition to licensing clinical laboratories, the staff of the Laboratory Field Services issue licenses to clinical laboratory personnel. The staff at the Laboratory Field Services review personnel license applications and schedule applicants to take examinations only after they have met educational and training requirements for the license class covered by the exam. Applicants are issued licenses after successfully completing the exam. The staff of the Laboratory Field Services issue licenses to trainees, technologists, and laboratory directors. Statutory requirements vary for the different positions. Technologists require a minimum of a baccalaureate degree or its equivalent and 52 weeks of experience. Licenses for laboratory directors require an advanced college degree and at least four years of experience. Examinations for the technologist positions are limited to written questions while examinations for the more advanced license classes include both written and oral questions. However, no examination is required for the histocompatibility laboratory director. These laboratory directors can only direct laboratories that only perform histocompatibility testing.

We reviewed records maintained by the Laboratory Field Services to determine the number and type of licenses issued annually. Table A-1 provides the number and type of licenses issued from calendar year 1986 through calendar year 1988.

Table A-1 **An Estimate of Facility and Personnel Licenses Issued by the Laboratory Field Services, Calendar Year 1986 Through Calendar Year 1988**

	1986	1987	1988
Total Clinical Laboratory Licenses	**2,057**	**2,048**	**2,040**
Total Biologic Facility Licenses	**144**	**153**	**160**
Personnel Licenses			
Histocompatibility laboratory director	13	13	13
Clinical laboratory bioanalyst	245	225	214
Clinical chemist	57	58	60
Clinical microbiologist	27	29	30
Clinical laboratory toxicologist	6	7	8
Clinical laboratory technologist	22,622	22,381	22,067
Clinical laboratory technologist, limited	1,096	1,111	1,124
Clinical laboratory technologist, trainee	1,900	1,900	1,850
Total Personnel Licenses	**25,966**	**25,724**	**25,366**

The Inspection Program

The Laboratory Field Services conducts unannounced inspections of laboratories. Section 1220 et seq. of the California Business and Professions Code states that the department may employ special examiners and implement regulations to conduct examinations. In fiscal year 1988-89, the department authorized the Laboratory Field Services to employ 12 examiners whose primary function was to inspect laboratories. In addition, the Laboratory Field Services has developed a checklist of items that these examiners review during each laboratory inspection. During these inspections, the Laboratory Field Services' examiners verify, among other things, that a laboratory has the proper facilities, follows sound quality control procedures, and employs licensed personnel.

State statutes and regulations do not require the staff of the Laboratory Field Services to conduct laboratory inspections with any specified frequency. However, the department does have a contract with the federal government that requires that 60 percent of all laboratories that participate in the Medicare and

Medicaid programs (Medicare laboratories) be inspected every year to ensure compliance with federal regulations. The staff at the Laboratory Field Services have developed a priority system to assist in scheduling laboratory inspections. Department examiners' first priorities include inspections of laboratories that are applying for their first license and inspections of laboratories that are included in the contractual agreements with the federal government (the Medicare laboratories). Non-Medicare laboratories are scheduled for inspections only after the higher priority inspections have been scheduled.

Between January 1, 1987, and December 31, 1988, examiners of the Laboratory Field Services inspected about 85 percent of the laboratories known to be operating in the State. As shown in Table A-2, some of the laboratories that were not inspected in 1987 or 1988 have not been inspected since before 1975. These laboratories are primarily specimen collection centers or laboratories operated at a facility accredited by an organization such as the Joint Commission on the Accreditation of Hospitals. Accredited facilities are considered to have met conditions for participation in the Medicare and Medicaid programs.

Table A-2 **Distribution of Laboratories by Last Inspection Year for Medicare and Non-Medicare Laboratories**

Years of Last Inspection	Non-Medicare Laboratories	Medicare Laboratories	Total of Medicare and Non-Medicare Laboratories	As a Percentage of Laboratories Operating on December 31, 1988
1971-74	7	0	7	0.29%
1975-78	30	0	30	1.24
1979-82	81	0	81	3.35
1983-86	230	7	237	9.81
1987-88	1,219	841	2,060	85.30
Total Number of Laboratories Operating as of December 31, 1988	**1,567**	**848**	**2,415**	

How the Laboratory Field Services Ensures That Laboratories Correct Deficiencies Found During Inspections

When examiners from the Laboratory Field Services find deficiencies at laboratories during inspections, the laboratories are required to improve their performance. If the examiners find that a laboratory does not meet statutory and regulatory requirements, the laboratory must submit a written plan of corrective action. This plan states the actions that the laboratory plans to take to meet statutory requirements in each area of noncompliance. If the examiners determine that a laboratory has a significant number of areas that do not comply with statutory requirements or if the areas of noncompliance seriously impede the laboratory's ability to perform accurate tests, the examiners will conduct a follow-up inspection to verify that the laboratory has taken the necessary corrective action. If the laboratory does not take the required corrective action, the department can order the laboratory to stop providing the diagnostic procedure to the public. As shown in Table A-3, the department inspected about

1,000 laboratories each year from January 1, 1985, to December 31, 1988. In each year, only a small number of follow-up inspections were performed.

Table A-3 Number of Laboratory Inspections, Calendar Year 1985 Through Calendar Year 1988

	1985	1986	1987	1988
Routine Inspections	1,065	1,069	914	1,145
Follow-up Inspections	64	55	51	70
Total Inspections	**1,129**	**1,124**	**965**	**1,215**

NOTE: These figures include only routine and follow-up inspections, not initial licensing inspections, validation surveys, or investigations.

Types of Deficiencies Found During Laboratory Inspections

To determine how frequently examiners from the Laboratory Field Services determined that the laboratories were not complying with statutes and regulations and to determine whether the laboratories corrected the deficiencies identified during an inspection, we reviewed a random sample of 123 laboratories that examiners from the Laboratory Field Services inspected during the period from January 1, 1986, through December 31, 1988. We found that 108 (87.8 percent) of the 123 laboratories in our sample had at least one area that did not comply with statutes and regulations.

To determine the types of deficiencies that the examiners at the Laboratory Field Services detected during their laboratory inspections, we judgmentally selected a sample of 44 of the 108 inspections that revealed at least one area of noncompliance. We

found that examiners from the Laboratory Field Services found a variety of deficiencies. The two deficiencies found most frequently were that the laboratory did not perform all required quality control procedures or maintain sufficient documentation of these procedures and that the laboratory's procedure manuals were incomplete or were not reviewed annually by the director. We also found that the laboratory's correspondence with other laboratories or clients did not contain all the required information and that the laboratory did not follow procedures to ensure safety or that the facility was inadequate for the number of personnel and tests performed.

All 108 of the laboratories with areas of noncompliance submitted the required written plan of corrective action to the Laboratory Field Services, and all but one of the laboratories submitted plans that provided acceptable resolution of the deficiencies noted during inspection. In this one case, the department notified the laboratory that its plan of correction was unacceptable and that the laboratory must stop providing one of its diagnostic tests to the public until the laboratory corrected the deficiency. Since this laboratory participates in the Medicare and Medicaid programs, the department also informed the U.S. Department of Health and Human Services about the area of noncompliance and recommended that the laboratory not receive payments from the Medicare and Medicaid programs for that test until the laboratory corrected the deficiency.

Other Statutory Responsibilities

In addition to its responsibilities for regulating clinical laboratories, the Laboratory Field Services has additional responsibilities related to clinical laboratories and other facilities and personnel involved in health-related fields. These responsibilities include approving and monitoring the operation of certain types of health-related facilities and the personnel who work in these facilities. The Laboratory Field Services also approves facilities to perform specific types of blood tests and acts as liaison between

the Clinical Laboratory Technical Advisory Committee and the department.

Approving and Monitoring Certain Health-Related Facilities and Their Personnel

The Laboratory Field Services is responsible for approving the operation of biologic and human tissue preservation facilities, as well as facilities that keep or use animals for research. In addition, the Laboratory Field Services is responsible for approving and monitoring the operation of public health laboratories and certifying public health microbiologists.

Biologic Facilities: Biologic facilities collect, test, process, store, and distribute whole blood and whole blood derivatives. Section 1616 of the California Health and Safety Code requires that the department collect an annual license fee from each of the State's biologic facilities. In 1988, the biologic facility license fee was $915.32.[1] Before issuing the license, staff of the Laboratory Field Services must ensure that the facility meets requirements regarding the proper amount of space, appropriate equipment, properly qualified personnel, and complete procedure manuals. The department collects a fee for each biologic facility license. The facility must renew the license annually. The department can suspend or revoke the license for the violation of any of the laws and regulations governing biologic facilities. According to the Laboratory Field Services' records, during 1988 the Laboratory Field Services issued licenses to 160 biologic facilities in California.

[1] We reviewed the Laboratory Field Services' calculation of the annual biologic facility license fee and determined the department did not correctly calculate the license fees for calendar years 1988 and 1989. We brought this to the department's attention in a management letter.

Human Tissue Preservation Facilities: Human tissue preservation facilities collect, store, process, and distribute human tissues from deceased donors. The California Code of Regulations requires that the department approve the operation of a human tissue preservation facility. Before granting approval, staff of the Laboratory Field Services must ensure that human tissue preservation facilities are operated under the direct supervision of a California licensed surgeon and that the method the facility uses to process the tissues prevents the tissues from becoming contaminated, dangerous, or harmful. Facilities must renew the approval at the end of each calendar year but are not required to pay a fee to the department. According to the Laboratory Field Services' records, as of December 31, 1988, there were 30 approved human tissue preservation facilities in California.

Animal Research Facilities: With the exception of facilities that are subject to control by the U.S. government, facilities that keep or use animals for research must have and display a certificate of approval from the department. A staff member in the department's Division of Laboratories inspects animal research facilities to determine whether the facility meets the requirements contained in statutes and regulations. If the facility meets program requirements, staff of the Laboratory Field Services will issue the certificate of approval. The facility must renew the certificate 12 months from the date of issuance. Under the provisions of the Health and Safety Code, the application for the certificate of approval requires a fee; however, the department has not set one.[2] According to the Laboratory Field Services' records, as of December 31, 1988, there were 28 facilities in California certified by the department to keep or use laboratory animals.

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[2] We brought this to the department's attention in a management letter.

Public Health Laboratories: Public health laboratories are established and funded by cities or counties to protect the community against infectious diseases. They differ from clinical laboratories in that the diagnostic tests performed at clinical laboratories generally involve the medical condition of individual patients whereas public health laboratories work with the entire medical community to contain and control epidemics.

Under the provisions of the California Code of Regulations, public health laboratories must have and display a certificate of approval from the department to operate. Staff of the Laboratory Field Services must inspect the public health laboratory to ensure it has met the various equipment, personnel, procedure, and recordkeeping requirements. Examiners of the Laboratory Field Services are required to inspect public health laboratories to verify compliance with regulations, certify the public health microbiologists who work in these laboratories, and approve training facilities for the public health microbiologist trainees. There is no fee associated with a public health laboratory certificate or a public health microbiologist certificate, and neither are required to be renewed each calendar year. According to the Laboratory Field Services' records, as of December 31, 1988, there were 58 certified public health laboratories and 1,576 public health microbiologists in California.

Approving Facilities To Perform Certain Blood Tests

California statutes and regulations require that facilities need specific approval from the department to perform certain types of blood tests. Specifically, the California Code of Regulations requires facilities to obtain the approval of the department to perform legally required premarital and prenatal tests for syphilis. The California Code of Regulations also requires facilities to have the department's approval to perform Acquired Immune Deficiency Syndrome (AIDS) antibody testing.

The Laboratory Field Services grants these approvals after determining that the facility is enrolled in an approved proficiency testing program and is in compliance with the other state regulations covering the type of test that the facility will be performing. The facility must reapply for approval if there is a change of the facility's director or location or the facility is not complying with regulations. According to the Laboratory Field Services' records, as of December 1988, 878 facilities throughout the State had approval to perform premarital and prenatal tests for syphilis, and, as of October 1988, 255 facilities had approval to perform AIDS antibody testing.

Serving as Liaison Between the Clinical Laboratory Advisory Committee and the Department

The Laboratory Field Services is also responsible for the Clinical Laboratory Technology Advisory Committee (committee). The California Business and Professions Code established the committee to assist the department. The committee provides advice and makes recommendations for rules and regulations that will ensure proper enforcement of statutes and regulations. The committee consists of 14 members who are appointed by the director of Health Services from nominees solicited by the department. The committee includes 8 licensed clinical laboratory staff, 3 surgeons, 2 members of the public, and one public health microbiologist. Staff of the Laboratory Field Services serve as ex officio members. The Laboratory Field Services administers committee functions and provides the primary liaison between the committee and the director of the department.

Appendix B Disposition of Cases Opened by the Department's Office of Legal Services as a Result of Referrals by the Laboratory Field Services January 1, 1985 to August 19, 1989

The Legislature requested that the Office of the Auditor General provide information on the actions that the Department of Health Services (department) has taken against licensees who have violated statutes and regulations. We reviewed cases opened or resolved by the department's Office of Legal Services during the period from January 1, 1985, to August 19, 1989, as a result of referrals by the Laboratory Field Services. These cases are generally not related to the types of deficiencies found during routine inspections. The department took action against licensees for problems such as falsification of test results and the use of unlicensed personnel to perform diagnostic tests. As shown in Table B-1, the department has opened or resolved cases against four licensed laboratory facilities and ten licensed laboratory personnel during this period.

Table B-1 Disposition of Cases Referred to the Department's Office of Legal Services by the Laboratory Field Services, January 1, 1985 to August 19, 1989

	Type of License			
	Trainee	Technologist	Director	Facility
License Suspended	0	1	0	0
License Revoked	1	3	1	0
License Probation	0	1	0	0
Other	1	0	1	2
Action Pending	0	1	0	2
Total	**2**	**6**	**2**	**4**

In addition to the cases listed above, the department took action against two other laboratories. They were suspended from participation in the Medi-Cal program because they were found guilty of crimes involving fraud or abuse of the program.

Appendix C Information on Fees Charged for Licenses Issued by the Laboratory Field Services

The Legislature requested that the Office of the Auditor General provide information on an increase in license fees for clinical laboratory technologists in calendar year 1987. This appendix describes the statutory formula for the annual calculation of license fees for all clinical laboratories and clinical laboratory personnel. In addition, this appendix describes why the formula resulted in a large increase in fees.

Clinical Laboratory and Clinical Laboratory Personnel Fees

Table C-1 shows the fees charged by the Laboratory Field Services of the Department of Health Services (department) for clinical laboratory and clinical laboratory personnel licenses from calendar year 1985 through calendar year 1988. The change in fees is calculated by the department according to a statutory formula contained in Section 116 of the California Health and Safety Code.

Table C-1 **Clinical Laboratory and Clinical Laboratory Personnel License Fees Charged by the Department, Calendar Year 1985 Through Calendar Year 1988**

	License Fee			
License Type	1985	1986	1987	1988
Initial License Fees				
Laboratory director	$44	$44	$64	$66
Clinical laboratory technologist	27	27	39	40
Clinical laboratory technologist trainee	9	9	13	13
Clinical laboratory	172	171	250	256
Renewal License Fees				
Laboratory director	44	44	64	66
Clinical laboratory technologist	17	17	25	26
Clinical laboratory technologist trainee	5	5	7	7
Clinical laboratory	136	135	197	202

Table C-2 shows the percent change in the fees charged for all clinical laboratory and clinical laboratory personnel licenses. The largest increase occurred from calendar year 1986 through calendar year 1987.

Table C-2 Percent Change in Clinical Laboratory and Clinical Laboratory Personnel License Fees Charged by the Department, Calendar Year 1985 Through Calendar Year 1988

Year	Percent Change
1985	-8.510%
1986	-0.391
1987	+46.285
1988	+2.410

To verify the license fees charged by the department, we reviewed the department's calculation of the fee increases. The department calculates clinical laboratory and clinical laboratory personnel license fees by applying a formula as required by Section 116 of the California Health and Safety Code. The formula has two components. The first component, which we refer to as the "a" adjustment, is based upon the amount of change from one fiscal year to the next in the amount of state funds appropriated to the Laboratory Field Services. The "a" adjustment is specified as a percent in each year's state budget act. The second component, which we refer to as the "b" adjustment and is also a percent, is based upon the amount of change in the amount of federal funds available to the Laboratory Field Services from one federal fiscal year to the next. Each year, since 1984, the department has calculated the "b" adjustment.

Calculating the total adjustment in the fee from one calendar year to the next involves applying both the "a" adjustment and the

"b" adjustment to an amount that we will refer to as the "baseline amount." The baseline amount is determined by reducing the previous year's license fee by the previous year's "b" adjustment. Thus, calculating the license fee is actually a three-step process, which starts by first determining the current year's baseline amount. The discussion below illustrates this three-step process using the license fee calculation for clinical laboratory technologists for calendar year 1987. The following list presents the amounts and percents used to calculate the license fee:

1986 Fee	$27
1986 "b" component adjustment	+2.016 percent
1987 "a" component adjustment	- .115 percent
1987 "b" component adjustment	+ 46.4 percent

The following outlines the three steps in calculating the license fee for clinical laboratory technicians for 1987:

Step one - Calculate the "baseline amount":

Calculate the baseline amount by reducing the previous year's fee by the previous year's "b" adjustment. For the 1987 fee calculation, this resulted in the following computation:

$27 decreased by 2.016 percent equals $26.46.

Step two - Apply the current year's "a" adjustment:

Apply the current year's "a" adjustment to the current year's baseline amount. For the 1987 fee calculation, this resulted in the following computation:

$26.46 decreased by -.115 percent equals $26.43.

Step three - Apply the current year's "b" adjustment:

Apply the current year's "b" adjustment to the result of step two and round to the nearest whole dollar. For the 1987 fee calculation, this resulted in the following computation:

> $26.43 increased by 46.4 percent and rounded to the nearest dollar equals $39.00.

Therefore, this calculation shows that the 1987 fee for clinical laboratory technicians should have been $39.00.

A change in work requirements resulted in a smaller amount of federal funding, which resulted in a large increase in license fees in 1987. In federal fiscal year 1985-86, a contract between the federal government and the State required the State to inspect all independent laboratories that were covered by the contract. However, in federal fiscal year 1986-87, the requirement had been reduced to 60 percent of the independent laboratories. As a result, the federal government reduced the amount of funding available to the Laboratory Field Services for performing inspections of laboratories that participate in the Medicare and Medicaid programs. When the decrease in federal reimbursement was applied to the statutory formula, the result was a large increase in license fees for 1987.

Appendix D Estimated Revenues and Expenditures of the Laboratory Field Services

The Legislature requested that the Office of the Auditor General provide information on the revenues and expenditures of the Laboratory Field Services for the period from fiscal year 1985-86 through fiscal year 1988-89. Table D-1 presents the estimated revenues and expenditures of the Laboratory Field Services for the period from July 1, 1985, to June 30, 1989.

Table D-1 Estimated Revenues and Expenditures of the Laboratory Field Services, Fiscal Year 1985-86 Through Fiscal Year 1988-89

	1985-86	1986-87	1987-88	1988-89
Revenues and Reimbursements				
General fund revenue	$889,246	$1,233,891	$1,288,900	$1,387,501
Federal trust fund payments	691,030	625,531	578,645	633,142
Indirect costs paid by the federal government	19,846	16,622	19,411	15,190
Miscellaneous reimbursements	10,043	10,199	6,519	0
Total Revenues and Reimbursements	**$1,610,165**	**$1,886,243**	**$1,893,475**	**$2,035,833**
Expenditures				
Salaries and wages	$1,061,585	$1,062,779	$1,015,486	$1,137,494
Staff benefits	327,275	297,541	332,351	313,972
Travel	96,177	96,624	79,659	72,452
Operating expenses and equipment	164,593	236,554	258,291	337,507
Data processing cost distribution	39,882	130,525	106,718	65,059
Total Expenditures	**$1,689,512**	**$1,824,023**	**$1,792,505**	**$1,926,484**

SOURCE: Accounting records from the Department of Health Services

Estimated Revenues

We reviewed records and reports maintained by the Laboratory Field Services to estimate the number and type of licenses issued annually. Table A-1 (see page 35) presents estimates of the number of licenses issued for calendar years 1986, 1987, and 1988 by type of license. We estimated the revenues received by the department for facility and personnel licenses by multiplying the estimated number of licenses issued by the amount of fee collected for each type of license. Table D-2 presents the fees received by type of license for calendar years 1986, 1987, and 1988.

Table D-2 Estimated Revenues From Fees by Type of License, Calendar Years 1986, 1987, and 1988

Revenues	1986	1987	1988
Facility Licenses	$267,276	$404,719	$431,758
Personnel Licenses	484,805	701,910	723,848
Biologic Facility Licenses	102,602	112,831	125,399
Total Revenues Received	**$854,683**	**$1,219,460**	**$1,281,005**

NOTE: Because we estimate the revenues based upon the number of licenses issued in each calendar year and the department estimates revenues by fiscal year, our revenue data differ from the revenue data maintained by the department.

Estimated Expenditures

As described in chapters 1 and 2 and Appendix A, statutes and regulations require the staff at the Laboratory Field Services to perform a variety of functions. The professional staff at the Laboratory Field Services complete daily time reports, through which they keep track of the activities they perform each day. Using these reports, along with other records maintained by the department, we analyzed the expenditures of the Laboratory Field Services. As shown in Table D-3, for fiscal year 1985-86 through fiscal year 1988-89, we determined the percent of time that both professional and clerical staff spent on each of their various activities including licensing and inspecting clinical laboratories, monitoring proficiency test results submitted for clinical laboratories, licensing clinical laboratory personnel, conducting enforcement actions, performing administrative activities, and licensing and monitoring biologic facilities, tissue banks, and public health laboratories.

Table D-3

Estimated Percent of Time Spent on Various Activities by the Staff of the Laboratory Field Services Fiscal Year 1985-86 Through Fiscal Year 1988-89

	1985-86		1986-87		1987-88		1988-89	
	Professional Staff	Clerical Staff	Professional Staff	Clerical Staff	Professional Staff	Clerical Staff	Professional Staff	Clerical Staff
Clinical Laboratory Licensing								
Initial licensing	5.14%	11.96%	4.89%	11.96%	4.90%	11.96%	4.37%	11.96%
Routine facility inspections	38.32	29.79	37.05	29.79	38.83	29.79	39.54	29.79
Follow-up facility inspections	0.88	0.56	0.56	0.56	0.59	0.56	1.09	0.56
Proficiency test monitoring	4.99	3.85	4.11	3.85	5.22	3.85	5.52	3.85
Clinical Laboratory Licensing Total	**49.33**	**46.16**	**46.61**	**46.16**	**49.54**	**46.16**	**50.52**	**46.16**
Personnel Licensing	10.89	18.85	8.55	18.85	8.48	18.85	9.21	18.85
Biologic Facility Licensing and Monitoring	2.14	7.64	2.03	7.64	1.29	7.64	1.67	7.64
Tissue Bank Licensing and Monitoring	0.02	0.05	0.11	0.05	0.01	0.05	0.12	0.05
Public Health Laboratory Licensing and Monitoring	0.61	0.00	0.74	0.00	0.20	0.00	0.30	0.00
Other Program Activities								
Administrative activities	16.53	27.30	20.08	27.30	20.04	27.30	15.88	27.30
Enforcement actions	0.79	0.00	1.34	0.00	0.81	0.00	1.14	0.00
Disseminating program information	18.33	0.00	19.04	0.00	17.53	0.00	17.71	0.00
Laboratory Field Services' staff training	1.36	0.00	1.50	0.00	2.10	0.00	3.45	0.00
Other Program Activities Total	**37.01**	**27.30**	**41.96**	**27.30**	**40.48**	**27.30**	**38.18**	**27.30**
Grand Total	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**

Table D-4 allocates the expenditures of the Laboratory Field Services according to the percent of time charged by the staff. The allocated expenditures cover the period from fiscal year 1985-86 through fiscal year 1988-89.

Table D-4 Estimated Expenditures of the Laboratory Field Services, Fiscal Year 1985-86 Through Fiscal Year 1988-89

	1985-86	1986-87	1987-88	1988-89
Clinical Laboratory Licensing				
Initial licensing	$101,809	$97,074	$94,522	$93,350
Routine facility inspections	585,527	562,158	565,266	604,964
Follow-up facility inspections	13,091	8,869	8,844	15,832
Proficiency test monitoring	66,000	55,149	66,520	75,040
Total for Clinical Laboratory Licensing	**766,427**	**723,250**	**735,152**	**789,186**
Personnel Licensing	174,506	145,714	143,632	163,031
Biologic Facility Licensing and Monitoring	50,107	47,963	37,644	45,035
Tissue Bank Licensing and Monitoring	387	1,560	252	1,703
Public Health Laboratory Licensing and Monitoring	7,985	9,558	2,430	3,932
Other Program Activities				
Administrative activities	260,961	293,816	290,677	265,326
Enforcement actions	8,671	14,434	8,587	13,121
Disseminating program information	201,102	204,637	186,670	203,115
Laboratory Field Services' staff training	14,891	15,999	22,452	39,470
Total for Other Program Activities	**485,625**	**528,886**	**508,386**	**521,032**
Overhead Costs				
Operating expenses and equipment	164,593	236,554	258,291	337,507
Data processing cost distribution	39,882	130,525	106,718	65,059
Total Expenditures	**$1,689,512**	**$1,824,010**	**$1,792,505**	**$1,926,485**

DEPARTMENT OF HEALTH SERVICES
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November 22, 1989

Mr. Kurt R. Sjoberg
Acting Auditor General
660 J Street, Suite 300
Sacramento, CA 95814

Dear Mr. Sjoberg:

Thank you for providing the Department of Health Services with a copy of your draft report regarding the Laboratory Field Services (LFS) program. Secretary Allenby has asked that I respond to your letter of November 15, 1989.

Please find enclosed the Department's responses to the audit findings and recommendations.

I am hopeful that your independent review of the LFS program will be helpful in assisting the Department to more effectively oversee clinical laboratories in California. As noted in your report, though, this will require additional resources and some statutory changes.

Sincerely,

Kenneth W. Kizer, M.D., M.P.H.
Director

Enclosure

DEPARTMENT OF HEALTH SERVICES RESPONSES TO THE OFFICE OF THE AUDITOR GENERAL REPORT ENTITLED "THE LABORATORY FIELD SERVICES WITHIN THE DEPARTMENT OF HEALTH SERVICES IS NOT MEETING ALL OF ITS RESPONSIBILITIES TO REGULATE CLINICAL AND PHYSICIAN'S LABORATORIES"

I. **FINDING: The Laboratory Field Service oversight and review of testing is limited, it has not always taken action against clinical laboratories that have failed tests, and does not have a procedure to determine whether all appropriate physicians' laboratories participate in testing.**

RESPONSE: The Laboratory Field Services (LFS) program has one staff member to monitor and review approximately 19,000 proficiency testing results received annually. LFS utilizes its site survey evaluations of licensed clinical laboratories as the primary mechanism for determining the services provided and, therefore, the proficiency testing programs in which the laboratory must enroll. Physician office laboratories (POLs) are exempt from licensure and, thus, not subject to the Department's assessment. Under these circumstances, there is no means by which the Department can determine the number of POLs operating, the services provided, and the extent of participation in a proficiency testing program.

Further, one staff person can monitor proficiency test results of only a portion of the licensed clinical laboratories and, as a result, is just not available to monitor proficiency test results of the unlicensed POLs. The Department has not created any additional positions for staff to monitor proficiency tests because: (1) an automated proficiency testing monitoring system is being implemented; (2) the Department has been unsuccessful in its pursuit of legislative options for the enhancement of the LFS program; and (3) there have been higher priorities for the Department's limited General Fund allocation.

Automation as an alternative to assist in the monitoring of proficiency tests was documented as far back as 1975. One of the reasons for the delay in developing an automated system has been the Department's difficulty in obtaining proficiency test results from the three main testing services. The largest testing service now submits quarterly test results to the Department on computer tape in a usable format. However, the other two testing services still provide data which require considerable conversion processing. The Department is working with these two entities to modify their report formats.

The Department's Data Systems Branch anticipates that the new automated proficiency testing data system will be implemented by February, 1990. Initially, monitoring of quarterly test performance will apply to all laboratories providing services in chemistry, one of the most common areas of testing. All laboratories performing unsatisfactorily in any

given quarter of testing will be identified. In the initial phase, we anticiipate inclusion of an automated facility licensing function. In the second phase, we will implement the monitoring of all other proficiency testing areas, except cytology which will be handled by implementing an on-site biennial proficiency testing program.

II. **FINDING: The Department of Health Services has not always complied with state laws and regulations in calculating and depositing the license fees that it collects from clinical laboratories and clinical laboratory personnel.**

COMMENTS: The Department has not been able to comply with those requirements in the State Administrative Manual which require the endorsement of checks on the day of receipt, and the deposit of fees within five days of receipt. The Department receives approximately 2,000 clinical laboratory, and 25,000 clinical laboratory personnel license renewals within a two-month period after the expiration of the licenses on December 31. The bulk of these renewals are received in a four-week period. To process so many renewals, the Department authorizes the staff of the Department's Cashiering Unit to work overtime and to hire temporary staff to assist the permanent staff within that unit to process the renewal applications. The Department has requested that the Department of Finance grant an exemption from the requirement that checks, drafts, and money orders be endorsed the day of receipt.

At certain times, the volume of renewal applications received has been so large that the Department has not been able to follow normal departmental procedures for securing license fees. The fees, however, are kept in a locked cabinet in a locked, secured room.

If the clinical laboratory and clinical laboratory personnel licensing programs had staggered renewal dates, the Cashiering Unit would be better able to endorse and deposit the fees received within the requirements of the State Administrative Manual.

With respect to the calculation of fees, errors apparently occurred beginning in 1984. This was due to: (1) a complex and cumbersome formula which was adopted to calculate fees as required under Section 116 of the Health and Safety Code; and (2) the misapplication of the various subsections of Section 116 to the previous years' fees in determining the total fee adjustment for the current year. Although the formula remains, the applications have been corrected and the fees from 1984 to 1989 have been recalculated in order to determine the correct fees for 1990.

RESPONSE TO AUDIT RECOMMENDATIONS:

The following are the Department's responses to the recommendations appearing on Pages 23, 24, and 33 of the report.

Recommendation #1 (Page 23): Continue to develop an automated system to evaluate proficiency test results as long as the new system will be compatible with new federal requirements that will be taking effect in 1990.

RESPONSE: The Department concurs. The first phase of the automated proficiency testing monitoring system is expected to be implemented by February, 1990. Initially, the system will identify, on an ongoing quarterly basis, all of the laboratories which have demonstrated unsatisfactory performance in chemistry tests. (As stated above, chemistry tests are one of the most common laboratory procedures used for diagnostic purposes.). The initial phase also includes an automated facility licensing function. The second phase will implement the monitoring of the remaining proficiency testing performance areas.

The automated data system is being designed to allow for the expansion of its data base, including the number of test results analyzed, in order to accommodate the expected increase in proficiency testing requirements under the new amendments of the Clinical Laboratory Improvement Amendments of 1988 and the federal Medicare Program. The Department will continue to work closely with the Health Care Financing Administration to ensure federal program needs will be met.

Recommendation #2 (Page 23): Promptly evaluate all proficiency test results for clinical laboratories and physicians' laboratories. To do this, the Laboratory Field Services should obtain additional staff until the automated system is operational.

RESPONSE: The Department concurs that proficiency testing results should be evaluated on a timely basis. The Department has been pursuing legislative avenues for the enhancement of LFS programs which would include improved proficiency testing monitoring. To date, those efforts have not been successful.

To the extent that resources permit, the Department will pursue other options for obtaining additional staff to support proficiency testing activities until the automated system is available. Further, the Department will evaluate its resource needs with the automated system in place.

Recommendation #3 (Page 24): Develop a procedure to verify that physicians' laboratories are enrolled in proficiency testing for all diagnostic tests that Laboratory Field Services monitors.

RESPONSE: The Department concurs. It is estimated that as many as 7,000 unlicensed POLs may be operating in California. LFS does not visit these unlicensed facilities, nor does LFS have the statutory authority or the resources to do so. The Department is considering options for determining compliance with the proficiency testing requirement by the unlicensed POLs. We will enter into discussions with appropriate medical associations to determine the best methods to obtain the information.

Recommendation #4 (Page 24): Require all laboratories which fail proficiency tests to stop providing the applicable diagnostic tests to the public as soon as the staff at the Laboratory Field Services determine that the laboratories are not passing proficiency tests.

RESPONSE: The Department concurs. When the new data system is made available, the Department should be able to accomplish this in a timely fashion.

Recommendation #5 (Page 33): Properly apply the formula described in Section 116 of the Health and Safety Code to calculate the license fees for clinical laboratories and clinical laboratory personnel. Because the formula relies on data from the previous year's calculation of license fees, the Department should calculate the 1990 license fees only after correctly applying the statutory formula to all annual fees incorrectly calculated during the period from 1984 to 1989.

RESPONSE: The Department has already instituted the proper application of Section 116 of the Health and Safety Code in determining the correct licensing fees for clinical laboratories and clinical laboratory personnel. Calculation of the 1990 fees was based upon a recalculation of fees from 1984 to 1989 based upon proper application of Section 116.

Recommendation #6 (Page 33): Seek legislation that would allow for staggered expiration of licenses so that the work load of the Department's Cashiering Unit would be distributed more evenly throughout the year and, thus allow the Cashiering Unit to promptly endorse and deposit fees.

RESPONSE: The Department will explore the feasibility of adopting staggered expiration of licenses held by clinical laboratory facilities and personnel licenses. In addition to staggered billing, the Department will explore the possibility of having the data for the remittance processing system automated.

cc: Members of the Legislature
Office of the Governor
Office of the Lieutenant Governor
State Controller
Legislative Analyst
Assembly Office of Research
Senate Office of Research
Assembly Majority/Minority Consultants
Senate Majority/Minority Consultants
Capitol Press Corps